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March 9, 2020

VIA ECF

Honorable Robert Kugler, U.S.D.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 4D
4th and Cooper Streets
Camden, NJ 08101

Honorable Joel Schneider, U.S.M.J.
U.S. District Court - District of New Jersey
Mitchell S. Cohen Building & US Courthouse
1 John F. Gerry Plaza, Courtroom 3C
4th and Cooper Streets
Camden, NJ 08101

Re: IN RE: VALSARTAN, LOSARTAN, & IRBESARTAN PRODUCTS LIABILITY LITIGATION
Civil No. 19-2875 (RBK/JS)

Dear Judge Kugler and Judge Schneider:

Plaintiffs respectfully submit the following proposal for an initial class certification procedure and trial plan for the economic loss consumer claims.

Plaintiffs propose that the Court proceed initially with a track for Class Certification and trial of the economic loss claims focused on ZHP and all defendants in the distribution chain that involved the sale of ZHP's active pharmaceutical ingredient ("API"). This is a logical starting point for multiple reasons including but not limited to: ZHP was the largest valsartan market share API manufacturer, and ZHP API appears to have the most extensive contamination and highest contamination levels, simplifying the proofs at trial. At the same time, overall discovery would continue, with an eye toward future similar tracks for the other API manufacturers and their distribution chains. The Defendants in the ZHP track would be as follows:

- **The ZHP Track**
  - Defendant *ZHP* manufactured API and its own finished dose VCDs.
  - Defendants *Torrent* and *Teva* each purchased API from ZHP, and sold their own finished dose VCDs that contained ZHP API.
  - Defendants *Solco*, *Huahai US*, and *Prinston* distributed ZHP's finished dose VCDs that contained ZHP API.
  - Wholesaler Defendants (*AmerisourceBergen, Cardinal Health*, and *McKesson*) to the extent they purchased and resold VCDs that contained ZHP API.

- Retail Pharmacy Defendants (*CVS, Walgreens, Walmart, Rite-Aid, Express Scripts, Kroger, OptumRx, Albertsons,* and *Humana*) to the extent they purchased and resold VCDs that contained ZHP API.

A graphic presenting this track is attached as Appendix A hereto.

I. Legal Overview and Precedent

Plaintiffs may propose a class definition, using objective criteria, as they deem appropriate under Rule 23. Even after class certification briefing has occurred, Rule 23 permits modification of class definitions. *Messner v. Northshore Univ. HealthSystem,* 669 F.3d 802, 811 (7th Cir. 2012). Accordingly, Plaintiffs submit this proposal with the intent of establishing a practical, efficient initial class to facilitate the Court's stated goal of proceeding with a focused trial in the first instance, reserving all rights to ultimately define the proposed class(es), and brief the motion(s) for class certification accordingly, and in concert with the discovery Plaintiffs receive in the coming months.[1] In this context, and answering a point recently raised by the defense, the Economic Loss Plaintiffs' master consolidated complaint is an administrative summary of the Economic Loss Plaintiffs' claims, and does not require Plaintiffs to define the class in a particular way. *See, e.g., In re Wirebound Boxes Antitrust Litig.*, 128 F.R.D. 262 (D.Minn.1989).

Management of complex MDLs involving numerous pharmaceutical Defendants and multiple classes by creating multiple tracks is well within the Court's discretion, and has been done before, with great success. For example, in the seminal *AWP* case, involving over 15 Defendants and over 200 drugs, the Court entertained certification motions and then created two separate tracks for trial. *See In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456, No. 1:01-cv-12257 (D. Mass.). As to the first track, Judge Saris conducted a bench trial and issued findings of fact and conclusions of law for the first track, which allowed the Parties to more efficiently negotiate resolution as to the second track. *Id.* Examples of other class action cases that segregated the case management (and class certification) into separate groupings include:

- *In re Automotive Parts Antitrust Litig.*, MDL No. 2311, No. 2:12-md-2311 (E.D. Mich. 2012) (dividing by auto part type and Plaintiff type);
- *In re Blue Cross Blue Shield Antitrust Litigation*, MDL No. 2406, No. 2:13-cv-2000 (N.D. Ala.) (segregating into two tracks based on plaintiff type, and then further dividing each track into sub-classes based on regional area);
- *In re Takata Airbag Products Liab. Litig.*, No. 15-md-2599 (S.D. Fla.) (dividing the case by car manufacturer);
- *In re: Checking Account Overdraft Litigation*, MDL No. 09-md-02036 (S.D. Fla.) (June 8, 2015) (dividing by Banks who engaged in similar conduct); and

[1] Under Rule 23, the Court, on its own authority, may add additional named plaintiffs or modify the class definition. It may also alter or amend its order affirming or denying class certification at any point before final judgment. *In re Nat. Football League Players Concussion Injury Litig.*, 775 F.3d 570, 586 (3d Cir. 2014).

- *In re Disposable Contact Lens Antitrust*, 329 F.R.D. 336 (M.D. Fla. 2018) (dividing by contact manufacturer and state purchased).

II. Why API-Focused Class Certification and Trial Tracks Make Sense

Important common issues in this litigation center on not only the API-level of manufacturing, but the obligations and duties that attach at each separate step in the drug manufacturing chain. Common evidence will seek to answer common questions, for example:

- What was the cause(s) of the contamination? (The answer to this question will likely vary to an extent as between API manufacturers).
- Were the API manufacturer's processes sufficient to ensure contamination would not occur?
- Were the API manufacturer's quality assurance and quality control measures sufficient?
- Was the API or finished dose manufacturer compliant or not compliant with current Good Manufacturing Practices (cGMPs), and/or were the drugs adulterated, and the reasons?
- What did each defendant know about the contamination of the API or VCDs?
- Was each defendant (API manufacturer, finished dose manufacturer, wholesaler, or retail pharmacy) compliant or non-complaint with federal regulations, including the Drug Supply Chain Security Act, and how do violations of those obligations relate to product that was contaminated with a known carcinogen?
- Did any defendant (API manufacturer, finished doe manufacturer, wholesaler, or retail pharmacy) make any express or implied warranties to consumers? Did such defendants breach their warranties in selling valsartan API, or VCDs?
- Did each defendant that sold API or VCDs wrongfully profit by selling contaminated API or VCDs?
- Is there a common methodology that can be applied for evaluating and calculating class members' damages?
- Did any defendant knowingly or recklessly conceal the truth about contaminated API or VCDs?
- Did any Defendant's conduct rise to the level of warranting punitive or exemplary damages?

The same evidence as to a given API Manufacturer Defendant will necessarily bear on the liability of downstream purchasers and resellers. Thus, organizing class certification by API manufacturer will result in significant efficiencies.

Class Certification will be sought by the appropriate representative plaintiffs as to all issues, liability and damages, followed by a single trial of a class or subclass as against all Defendants in the ZHP Track, which will result in a single liability verdict as to each of them. Thereafter, if the Plaintiffs prevail, the damages portion of the trial can proceed at a reasonable time thereafter. This will allow the Court to address segments of the case in an orderly fashion.

Notably, under Plaintiffs' proposal, each downstream defendant (wholesalers, retail pharmacies) will be subject to certification and adjudication of claims against them in each trial, but only for the VCDs they handled that contained API from the pertinent API manufacturer. For example, in a ZHP API certification and trial, Walgreens will not face liability or damages for anything but VCDs it dispensed that contained ZHP API. An entity like Kroger, who claims it only dispensed Camber/Hetero VCDs, would not be part of the class certification briefing or trial for the ZHP Track. This is yet another illustration of the organizational efficiency of this approach.

Certifying and trying claims with all levels of the distribution chain is also advantageous for allocation reasons. It may be that the jury is asked to allocate liability and/or damages.[2] Further, it is possible that liability established in these cases will be joint and several as to certain Defendants. Thus, this allows all potentially liable parties to be subject to a coherent verdict in a single trial (for the class or subclass tried).

Finally, certification and trial of a class or subclass that encompasses claims against the chain of sellers or resellers of ZHP's API, obviates any potential concerns about one-way intervention. That is, a trial on behalf of all consumers who purchased a VCD that contained ZHP API will necessarily result in a judgment applicable to all such consumers (absent opt-outs) and all defendants who sold ZHP API. Thus, there is no risk that a judgment on less than all such consumers' claims might not be preclusive or binding as to others, as Defendants have argued might be the case if an individual economic loss consumer's claim was tried to verdict individually before any class certification decision was rendered. *See, e.g.*, *Koehler v. USAA Cas. Ins. Co.*, No. 19-715, 2019 WL 4447623, at *4-7 (E.D. Pa. Sept. 17, 2019) (discussing one-way intervention vis-à-vis pre-certification). In fact, Plaintiffs agreed to certification of the class or subclass for trial (subject to the Court's determination) in an effort to reach common ground with the Defendants, who voiced this concern during the meet and confer process.

III. Timing of Class Certification and Trial

The ongoing discovery, Class Certification briefing, and trial preparation can proceed in concert, with the ruling on Class Certification to be followed by the substantive trial briefing, inclusive of dispositive motions,[3] and the trial or trials. This will allow those Defendants implicated in the initial trial to advance whatever substantive motions they choose, as part of this process. The exact time periods and dates can be determined on a reasonable basis, taking into account the pace of discovery, and the Court's preferences. At the same time, discovery and ongoing resolution of issues related to the wider issues and litigation can continue unimpeded, and the Court can identify other tracks or important issues to be focused on as the litigation proceeds.

[2] Due to the existence of indemnity agreements or other joint defense agreements that potentially shift liability among the Defendants up and down the chain of distribution, it simply makes sense to have all the real parties in interest at counsel table during the certification and trial process. It should be noted that Plaintiffs have yet to see such obviously relevant documents from API and Finished Dose Manufacturer Defendants; and Wholesaler and Retailer Defendants refuse to produce them.

[3] Having dispositive motions follow class certification briefing will allow the parties to efficiently brief dispositive motions as to only the claims that were certified.

To the extent the Court subsequently certifies the other classes (see *infra* Part IV), Plaintiffs can then prepare those cases for trial, following the roadmap already set out by the ZHP track.

IV. Staggered Class Certification Briefing for Subsequent API Tracks

Given its role in the market (having achieved over 50% of the valsartan market), and the size of the putative class, at this point in time, and reserving all of their rights as discovery proceeds, Plaintiffs believe the ZHP Track should proceed to class certification and trial first. Similar to how Judge Saris managed the *AWP* case as (discussed *supra* at I), this will allow the Court to make legal rulings that will assist the parties in more efficiently resolving the issues related to the other Defendant groupings Plaintiffs propose. Indeed, Plaintiffs' proposal protects the downstream defendants' ability to raise new issues that may present themselves based on potentially differing fact patterns as between the API defendants. It also makes the process efficient by allowing the Court to otherwise apply its rulings without duplicating efforts. Also, this situation would be no different than where an MDL Court issues *in limine,* and other substantive and dispositive rulings in one product liability trial, and then references or relies on those same rulings in subsequent trials, including as to other parties.

Plaintiffs propose that certification and trials be staggered such that the parties have sufficient time to brief the issues, and engage in focused trials addressing each API grouping. Plaintiffs propose that the remaining Defendants be organized in the manner delineated in Appendices B-D, stemming from the initial source of the API. In comparison, Defendants' anticipated proposal (based on discussions to date), for class certification and dispositive briefing to proceed as to all parties would result in maximum inefficiency. That structure would require the parties to spread their resources and focus to all parties, and to issues that would likely never have to otherwise be addressed, should Plaintiffs' proposal crystalize the issues for the overall litigation as anticipated.

V. Conclusion

For the foregoing reasons, Plaintiffs respectfully request that the Court structure the ongoing litigation as proposed herein.

Respectfully,

/s/ Adam M. Slater	*/s/ Conlee S. Whiteley*	*/s/ Ruben Honik*	*/s/ Daniel Nigh*
Adam M. Slater	Conlee S. Whiteley	Ruben Honik	Daniel Nigh

MDL Plaintiffs' Co-Lead Counsel